REMARKS

Claims 1 to 16 are pending. Claim 14 is canceled and no claims are allowed.

1. The listing of references in the specification is indicated to be an improper information disclosure statement. This is particularly due to U.S. application Serial No. 10/719,632 being referenced on page 8 of the specification, but not listed on Form 1449. However, the examiner must have considered this application to some extent as it is used later to reject claims based on the judicially created doctrine of obviousness-type double patenting.

2. The drawings are objected to under 37 CFR 1.83(a) for failing to show appropriate detail as described in the specification. Specifically, the examiner states that it is difficult to identify any important structural characteristics of the inventive surface coatings in Figs. 8 to 12. Replacement drawings accompany this amendment.

3. Claims 1 to 7 and 11 to 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 5 and 22 of co-pending application Serial No. 10/719,632. However, the carbonaceous outer coating applied to the intermediate coating in the co-pending application is patentably distinct from the applicant's presently claimed invention.

Independent claims 1, 11 and 13 have been amended to call for the carbon-containing coating comprising amorphous carbon having a random carbonaceous structure with no covalent bonding. In contrast, the co-pending application claims

crystalline carbon in the form of nanotubes. At page 9, lines 16 to 22, a crystalline structure is described as one having short-range order in two (graphitic) or three (diamond) dimensions. Although the competing inventions share carbon as a common material, the various allotropes of carbon are unique. In other words, the claimed structures in each application are to the unique structure and morphology of a carbonaceous allotrope, not to the element carbon.

Reconsideration of this rejection is requested.

4. Claim 8 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 5 and 22 of co-pending application Serial No. 10/719,632 in view of Malonek et al. (U.S. Patent No. 6,292,704). The presently amended form of independent claim 1, from which claim 8 depends, and the arguments set forth in section 3 above, negate the basis of this rejection.

Reconsideration of this rejection is requested.

5. Claims 9, 10 and 16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 5 and 22 of co-pending application Serial No. 10/719,632 in view of Frericks et al. (U.S. Pub. No. 2004/0127966). The presently amended form of independent claims 1 and 13, from which these claims depend, and the arguments set forth in section 3 above, negate the basis of this rejection.

Reconsideration of this rejection is requested.

6. Claims 1 to 5, 7, 8 and 11 are rejected under 35 USC 102(b) as being anticipated by Malonek et al. This patent teaches myocardial electrodes comprising a substrate of "a material selected from the group of platinum, platinum-iridium, titanium and carbon." A coating of a high-capacitance material selected from iridium oxide, titanium nitride, paralytic carbon, and activated carbon is supported on the substrate. As pointed out by the examiner, these coating materials are "intended to enhance electrical efficiency and to help minimize fibrotic tissue growth response." See column 1, lines 58 to 62.

The applicant does not dispute that this was the current state of the art prior to his invention. In fact, dependent claims 2 and 3 call out that the substrate is of tantalum, titanium, zirconium, iridium, platinum, and niobium. Dependent claim 4 calls out a host of intermediate materials that can be coated onto the substrate including iridium oxide and titanium nitride. This is as taught by Malonek et al. and discussed by the examiner in the office action. However, independent claims 1 and 11 have been amended to further call out a carbon-containing coating adhered to the intermediate (claim 4) coating. This coating is of amorphous carbon having a random carbonaceous structure with no covalent bonding. It can also be amorphous carbon doped with nitrogen. The definition of amorphous carbon is found in the specification at page 9, lines 16 to 22.

One inventive aspect of the presently amended claims is that the amorphous carbon intrinsically has low polarization and high biocompatibility while conforming to the roughness of the high surface area intermediate layer, such as one of titanium nitride, as discussed at page 7, lines 7 to 24. Advantages of the presently claimed invention are set forth in

the examples beginning on page 10. In particular, the polarization results of a substrate of sintered Pt/10% Ir are -440 mV. On the other hand, the polarization of a sintered Pt/10% Ir substrate coated with TiN and then an amorphous layer of carbon according to the claimed invention is -75mV. If the amorphous carbon is doped with nitrogen, polarization drops even further to -45 mV.

Accordingly, the Malonek et al. patent neither anticipates amended independent claims 1 and 11, nor would they have been obvious in light of this prior art. Claims 2 to 5, 7 and 8 are patentable as hinging from an allowable base claim.

Reconsideration of this rejection is requested.

7. Claims 1 to 7 and 11 to 15 are rejected under 35 USC 102(e1) as being anticipated by O'Brien et al. (U.S. Pub. No. 2005/0075708). The O'Brien et al. publication discloses implantable electrodes comprising a substrate, an intermediate coating and a carbon-containing coating adhered to the intermediate layer. As pointed out by the examiner, the substrate is selected from a variety of conductive metals provided with any one of a host of intermediate coating materials including titanium nitride. Carbonaceous nanotubes are then covalently bonded to the intermediate coating (paragraph 0009). As discussed in paragraph 0008, the nanotubes are in the form of single-walled nanotubes, multi-walled nanotubes, nanotube ropes, carbon whiskers, and combinations thereof. In any event, the result is a layer consisting of a multitude of nanotubes, each attached at one or both ends to the intermediate coating on the substrate.

In that respect, it is clear that this published reference and the presently claimed invention share carbon as

a common material. However, the various allotropes of carbon are unique. Amended independent claims 1, 11, and 13 are now directed to a unique structure and morphology of a carbonaceous allotrope, not to carbon per se.

Accordingly, amended independent claims 1, 11 and 13 are neither anticipated by the O'Brien et al. publication, nor obvious in light of it. Claims 2 to 5, 6, 7, 12 and 15 are patentable as hinging from an allowable base claim. Claim 14 is cancelled.

Reconsideration of this rejection is requested.

8. Claim 8 is rejected under 35 USC 103(a) as being unpatentable over O'Brien et al. in view of Malonek et al. This claim depends from independent claim 1 which, in its presently amended form, is patentable over O'Brien et al. The teachings in Malonek et al. regarding modifying the surface area of the substrate do not affect this patentability. Therefore, claim 8 is patentable as hinging from an allowable base claim.

Reconsideration of this rejection is requested.

9. Claims 9 and 10 are rejected under 35 USC 103(a) as being unpatentable over Malonek et al. and O'Brien et al. in view of Frericks et al. These claims depend from amended independent claim 1, which is patentable over both Malonek et al. and O'Brien et al. The inclusion of Frericks et al.'s teachings regarding the prescribed thicknesses for the ceramic and oxidation protective layers does not destroy this patentability. Accordingly, claims 9 and 10 are patentable as hinging from an allowable base claim.

Reconsideration of this rejection is requested.

10. Claim 16 is rejected under 35 USC 103(a) as being unpatentable over O'Brien et al. in view of Frericks et al. This claim depends from amended independent claim 13, which is described in section 7 above as being patentable in light of O'Brien et al. As before, Frericks et al.'s teaching regarding the prescribed thicknesses for the ceramic and oxidation protective layers does not destroy this patentability. Accordingly, claim 16 is patentable as hinging from an allowable base claim.

Reconsideration of this rejection is requested.

11. Claims 13 to 16 are rejected under 35 USC 103(a) as being unpatentable over Malonek et al. in view of Frericks et al. as applied to claims 9 and 10 above, and further in view of Edeling et al. (U.S. Patent No. 4,612,100) and Schaldach et al. (Biomed. Technik 34 (1989), 185-190). The Edeling et al. patent describes at column 3, lines 48 to 58 that "the electrode consists of platinum having a surface layer consisting at least partially of vitreous carbon applied via the sputtering technique." This means that the vitreous carbon is sputter deposited directly onto the platinum substrate because it "adheres well to an electrode and very well to a platinum electrode in particular" (column 3, lines 24 to 26). The result is an implantable electrode having very low polarization losses at the boundary surface between the electrode and the tissue (column 3, lines 30 to 34).

As pointed out by the examiner, Frericks et al. at paragraph 0003 disclose that a "diamond-like carbon can be deposited using a laser, among other things. It is furthermore disclosed that the entire electrode head may be coated with a diamond-like carbon layer and thereafter the stimulation surfaces may be freed, as desired, by

photoetching." From this teaching, one skilled in the art would have understood that while diamond-like carbon is "extremely biocompatible" it does not have the requisite porosity to serve as an implantable conductive surface as taught by Frericks et al. Instead, the stimulation surface must be "freed" through further processing to provide a high surface area material.

Schaldach et al. relates to pacemaker electrodes made of titanium nitride sputter-deposited onto a substrate as a micro-crystalline surface structure. The applicant acknowledges that the good conductivity and high specific surface area of TiN provide favorable polarization and sensing properties. This is discussed at page 2 of the application in relation to U.S. Patent No. 4,602,637 to Elmqvist.

In that light, the applicant respectfully disagrees with the examiner's conclusion that "it would have been obvious to one of ordinary skill in the art at the time of the invention to employ a sputtering method as taught by Edeling et al. and Schaldach et al. to deposit the carbon-containing coating onto the intermediate layer of Malonek et al. . . . " None of the secondary references of Edeling et al., Frericks et al. and Schaldach et al. discuss the provision of an intermediate layer between the substrate and their disclosed coating layer, regardless how it is deposited. Simply, there is no suggestion or hint that the vitreous carbon outer layer of Edeling et al. and the diamond-like carbon of Frericks et al. would be useful in an electrode as defined in the presently amended claims. Looked at a different way, these references are devoid of any teaching that would lead one skilled in the art to realize that an intermediate material, such as one of titanium nitride, can be improved in any manner by the provision of an amorphous carbon coating thereon.

The motivation for the applicant's invention came about after understanding that in high surface area stimulation materials such as titanium nitride there can be a certain percentage of unreacted titanium. Over time, this titanium reacts with the body environment to form $Ti_2O_5$, which is comparatively resistive with high polarization. Amorphous carbon having relatively little porosity on its own, but exhibiting excellent conductivity, prevents this parasitic reaction from taking place without compromising the inherently good conductivity of the intermediate layer. In that respect, none of the secondary prior art references appreciated this problem; much less propose a solution, regardless the deposition process for the carbonaceous outer layer. There is simply no hint or suggestion in Edeling et al., Frericks et al. or Schaldach et al. that an intermediate coating exhibiting good biocompatibility and low polarization, such as of titanium nitride, can be improved upon by an outer coating of carbon in any of its allotropic forms.

In respect of Edeling et al., there are no unreacted species on the platinum electrode. However, it is now known that a platinum electrode surface can be improved by deposition thereon of a high surface area intermediate coating such as Malonel et al.'s titanium nitride material. Frericks et al.'s step of "freeing" the diamond-like carbon runs counter to the purpose of the pending claims to block communication of the intermediate highly porous layer with body fluid by deposition of a low polarization, but highly biocompatible outer layer. Freeing the outer carbonaceous surface will allow penetration of body fluid to the electrode substrate, which negates one of the problems solved by the present invention.

In that light, this rejection is based on a mosaic of prior art references each lacking an understanding that carbon, and particularly amorphous carbon, can be deposited onto an intermediate layer contacting a substrate to arrive at the invention set forth in amended independent claim 13. Instead, the examiner has supplied the missing part by relying on speculation and hindsight reasoning.

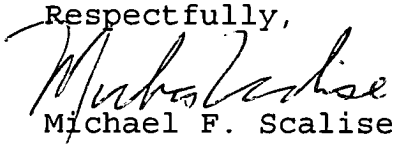
Accordingly, it is believed that under a fair reading of the prior art applied under a reasonable interpretation of the patent laws, amended independent claim 13 is allowable. Claims 15 and 16 are patentable as hinging from an allowable base claim. Claim 14 is cancelled.

Reconsideration of this rejection is requested.

12. The prior art made of record and not relied upon has been reviewed, but it is not considered more relevant than the cited references.

It is believed that claims 1 to 13, 15 and 16 are now in condition for allowance. Notice of Allowance is requested.

Respectfully,



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